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Exhibit 595

APPENDIX B

U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator

Springfield, VA 22152

September 13, 2012

IN THE MATTER OF

Walgreen Co.
15998 Walgreens Drive
Jupiter, Florida 33478

ORDER TO SHOW CAUSE AND
IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Walgreen Corporation ("Walgreens" or "Respondent") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration RW0277752, pursuant to 21 U.S.C. § 824(d), because such registration constitutes an imminent danger to the public health and safety. Notice is also given to afford Walgreens an opportunity to show cause before DEA in Arlington, Virginia, or a location designated by the Administrative Law Judge, on November 13, 2012 (if Walgreens requests such a hearing), as to why DEA should not revoke Walgreens's DEA Certificate of Registration RW0277752, pursuant to 21 U.S.C. § 824(a)(4), deny any pending applications for renewal or modification of such registration, and deny any applications for additional registration, pursuant to 21 U.S.C. § 823(b) & (e), because Walgreens' continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(b) & (e). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following nonexhaustive summary of facts and law (*see* 21 C.F.R. §§ 1301.36(e) and 1301.37(c), which DEA construes *in pari materia* in this context.)

1. Walgreens' Jupiter Florida Distribution Center is registered with DEA as a distributor in Schedules II-V pursuant to DEA Certificate of Registration RW0277752 at 15998 Walgreens Drive, Jupiter, Florida 33478. DEA Certificate of Registration RW0277752 expires by its terms on May 31, 2013. The Jupiter Distribution Center is one of 12 Distribution Centers owned and operated by the Walgreen Corporation,

headquartered in Deerfield, Illinois. Walgreens also operates more than 7800 Walgreens retail pharmacies in the United States.

2. Since at least 2009, the State of Florida has been the epicenter of a notorious, well-documented epidemic of prescription drug abuse. In July 2011, the Florida Surgeon General declared a Public Health Emergency based on the prescription pill epidemic which results in an average of seven overdose deaths per day in Florida. The drugs most commonly associated with this epidemic are typically prescribed at unscrupulous pain clinics by physicians acting outside the usual course of professional practice and include Schedule II pain relievers, such as oxycodone; Schedule IV benzodiazepines such as alprazolam, and Schedule IV muscle relaxers, such as carisoprodol. Frequently, these drugs are prescribed in large amounts and in combination with each other as "cocktails" popular with drug seeking individuals. *See East Main Street Pharmacy*, 75 Fed. Reg, 66149, 66153, (2010); *Paul H. Volkman*, 73 FR 30630, 30633-34, 30639 (2008), *pet. for rev. denied*, *Volkman v. DEA*, 567 F.3d 1215 (6th Cir. 2009).

3. Oxycodone is a dangerously addictive Schedule II controlled substance which is known to be highly abused and diverted in the State of Florida. According to the 2010 Florida Medical Examiner's Commission Drug Report, the drug that caused the most deaths in the state of Florida for 2010 was oxycodone (1,516 deaths), followed by benzodiazepines (1,304 deaths of which 981 were caused by alprazolam.)

4. Since 2009, Walgreens' Jupiter, Florida Distribution Center has been the single largest distributor of oxycodone products in Florida. At about the same time as the abuse of prescription drugs became an epidemic in Florida, Walgreens' Florida retail pharmacies, supplied by Respondent, commanded an increasingly large percentage of the state's growing oxycodone business. In 2010, only 3 Walgreens retail pharmacies were in the top 100 purchasers of oxycodone within Florida. In 2011, 38 Walgreens pharmacies made the top 100 and 6 were in the top 10. Through May 2012, 44 Walgreens pharmacies are in the top 100 oxycodone purchasers, all of them supplied by Respondent.

5. According to DEA records, in 2011, Walgreens operated 7,862 retail pharmacies in the United States. Sixteen of the top 25 largest Walgreens retail oxycodone purchasers, including the top 6 purchasers, were in Florida and supplied by Respondent. The following table shows these 6 stores and their yearly oxycodone purchases for 2009 through 2011:

Store # Location	Oxycodone Purchases by Dosage Unit 2009	2010	2011
1. 03629 Hudson, FL	388,100	913,900	2,211,700
2. 03099 Ft. Myers, FL	95,800	496,100	2,165,900
3. 06997 Oviedo, FL	80,900	223,500	1,684,900
4. 03836 Port Richey, FL	344,000	849,000	1,406,000
5. 04391 Ft. Pierce, FL	250,000	881,400	1,329,600
6. 04727 Ft. Pierce, FL	153,500	507,100	1,192,000

6. An ongoing DEA investigation of Respondent's distribution practices and policies, combined with both a general examination of dispensing at Walgreens Florida pharmacies as well as a detailed investigation of the dispensing practices at the six pharmacies identified above, demonstrates that Respondent has failed to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1). Respondent failed to conduct adequate due diligence of its retail stores, including but not limited to, the six stores identified above, and continued to distribute large amounts of controlled substances to pharmacies that it knew or should have known were dispensing those controlled substances pursuant to prescriptions written for other than a legitimate medical purpose by practitioners acting outside the usual course of their professional practice. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487 (2007) (revocation based in part on the respondent's recurring distributions of extraordinary quantities of controlled substances to entities that likely diverted the controlled substances by filling unlawful prescriptions, as well as the respondent's failure to conduct due diligence sufficient to protect against the diversion of the controlled substances it distributed).

7. DEA's investigation of Respondent also revealed that Walgreens failed to detect and report suspicious orders by its pharmacy customers, in violation of 21 C.F.R. §1301.74(b). 21 C.F.R. § 1301.74(b) (distributors are required to "design and operate a system to disclose to the registrant suspicious orders of controlled substances . . . suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."); *see also Southwood Pharm., Inc.*, 72 Fed. Reg. at 36,502 (finding that the respondent repeatedly violated federal regulations by failing to report suspicious orders). Walgreens knew or should have known about their obligations to report suspicious orders, as such obligations were spelled out in detail in three letters from DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including Respondent, on September 27, 2006, February 7, 2007, and December 27, 2007. The purpose and proper implementation of suspicious order reporting programs was further discussed in the industry's own trade association, the

Healthcare Distribution Management Association (HDMA), in "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances" published in 2008.[1]

8. Notwithstanding the ample guidance available, Walgreens has failed to maintain an adequate suspicious order reporting system and as a result, has ignored readily identifiable orders and ordering patterns that, based on the information available throughout the Walgreens Corporation, should have been obvious signs of diversion occurring at Respondent's customer pharmacies. *See* 21 C.F.R. § 1301.74(b); *see also Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487 (2007).

9. Respondent's practice with regard to suspicious order reporting was to send to the local DEA field office a monthly report labeled "Suspicious Control Drug Orders." Two reports were provided, one for suspicious orders of Schedule II drugs, another for suspicious orders of drugs in Schedules III through V. These reports were transmitted on Respondent's behalf from Walgreens Corporate headquarters in Deerfield, Illinois. Respondent's suspicious order report for December 2011 appears to include suspicious orders placed by its customers for the past 6 months. The report for just suspicious orders of Schedule II drugs is 1712 pages and includes reports on approximately 836 pharmacies in more than a dozen states and Puerto Rico. The reports are based on a formula that assigns an average monthly order for a particular drug, which is then multiplied by a "DEA factor" (which is always 3, regardless of the drug or the average order amount), resulting in a "Trigger" amount, above which orders for the month are reported as suspicious, along with a listing of all orders placed for the particular drug by the reported pharmacy for the month in which the "Trigger" amount was exceeded. This report from the Jupiter Distribution Center covers pharmacies in multiple states and Puerto Rico, yet the average order and trigger amount is the same for a particular drug regardless of the pharmacy's location, the population it serves, or the number of other pharmacies in the area.

10. As made clear in 21 CFR §1301.74(b), *Southwood*, and the December 27, 2007 letter to distributors from the Deputy Assistant Administrator for the Office of Diversion Control, suspicious orders are to be reported *as discovered*, not in a collection of monthly completed transactions. Moreover, commensurate with the obligation to identify and report suspicious orders as they are discovered is the obligation to conduct meaningful due diligence in an investigation of the customer and the particular order to resolve the suspicion and verify that the order is actually being used to fulfill legitimate medical needs. This analysis must take place *before* the order is shipped. No order identified as suspicious should be fulfilled until an assessment of the order's legitimacy is concluded. As such, Respondent's reports, consisting of nothing more than an aggregate of completed transactions, did not comply with the requirement to report suspicious orders as discovered, despite the title Respondent attached to these reports.

[1] See http://www.healthcaredistribution.org/gov_affairs/pdf_controlled/20081113_icg.pdf.

11. A review of the documents Respondent provided as evidence of its "due diligence" on the above listed six pharmacies, demonstrates that Respondent failed to conduct any meaningful investigation or analysis to ensure that the massive amounts of commonly abused, highly addictive controlled substances being ordered by these pharmacies were not being diverted into other than legitimate channels. In response to DEA requests, Respondent has been unable to provide any files related to any effort to adequately verify the legitimacy of any particular order it shipped to its customer stores.

12. Respondent's employee with overall responsibility for Schedule II drug operations (the "CII Function Manager"), raised questions within the corporation about what she correctly identified as unusually large orders for Schedule II narcotics placed regularly by several customer pharmacies. Based on the evidence available to DEA, none of these orders were reported to DEA as suspicious and all appear to have been shipped, without any further due diligence to verify their legitimacy. For example:

    a. In January 2011, Jupiter's CII Function Manager expressed concern about the enormous volume of 30 mg oxycodone being ordered by three stores, Walgreens #'s 7298, 3836, and 5018, concluding in an email to the "Manager, Rx Inventory Drug Stores" at Walgreens' Corporate Headquarters in Deerfield, Illinois, that she felt the stores needed "to justify the large quantity." With regard to store # 3836 in Port Richey, Florida, she noted that Respondent had shipped this store 3271 bottles of 100 count 30 mg oxycodone (i.e., 327,100 dosage units) in the 40 day period from 12/1/10 to 1/10/11, causing her to question *"how they can even house this many bottle[s]."* She then inquired of the same corporate manager: *"How do we go about checking the validity of these orders?"*

    b. Despite having raised these concerns from the distributor to a supervisor at corporate headquarters, none of these orders were reported as suspicious and there appears to have been no other inquiry conducted into the circumstances of the enormous amount of narcotics being shipped to store # 3836 in Port Richey, a town of less than 3000 people in a county with a population of only approximately 475,000. Despite the fact that a distribution center manager had raised questions about this store's ordering volume to a corporate manager in January 2011, the very next month, Respondent filled and shipped orders totaling another 285,800 dosage units of 30 milligram oxycodone to the same pharmacy. Again, there is no evidence of any due diligence conducted by Respondent or anyone else within the corporation to verify the legitimacy of these orders in order to fulfill their obligation to maintain effective controls against diversion.

13. According to documents received from Walgreens Corporate Headquarters, on April 2, 2012, Walgreens revised its suspicious order policy, but made the policy retroactively effective to January 1, 2012. The policy states, in pertinent part, that "Effective calendar year 2012, the Controlled Substance Order Monitoring and Prevention System prevents suspicious control drugs from being shipped to the stores. In calendar year 2012, because of the program mentioned, suspicious control drug reports are no longer generated as their shipment is prevented by the system."

14. This policy ignores the fact that the reporting requirement of 21 CFR § 1301.74(b) applies to *orders*, not shipments. A suspicious order placed by a customer pharmacy is made no less suspicious by application of a system designed to reduce or eliminate such orders prior to shipping. Construing the regulation this way defeats the essential purpose of the suspicious order requirement, which, as I stated in *Southwood*, is "to provide investigators in the field with information regarding potential illegal activity in an expeditious manner." 72 FR at 36501.

15. Respondent's local DEA field office within the Miami Field Division has not received a suspicious order report for any orders placed in 2012, despite the fact that Respondent has received and shipped multiple orders this year that, using the criteria Walgreens employed in 2011, would have exceeded the trigger amount previously used to report these sales.

16. The available evidence suggests that Respondent's abdication of its responsibilities as an individual registrant was at least facilitated by a push from Walgreens Corporate headquarters to increase oxycodone sales at its Florida retail pharmacies, all of which received their Schedule II controlled substances from Respondent. I also note that during the relevant time herein, Walgreens had in effect compensation programs for pharmacy employees in which bonuses were based on the number of prescriptions filled at the pharmacy. This bonus program, combined with a concerted, corporate directed effort to increase oxycodone sales, served as an incentive for pharmacists and pharmacy technicians to ignore the "red flags" of diversion presented by these prescriptions, many of which, in the proper exercise of the pharmacist's corresponding responsibility under 21 CFR §1306.04(a), should have resulted in a refusal to fill.

    a. In July 2010, Walgreens' corporate headquarters conducted an analysis of oxycodone dispensing for the prior month at its Florida retail pharmacies and produced an 11 page spreadsheet, ranking all Florida stores by the number of oxycodone prescriptions dispensed in June. The spreadsheet was sent to Walgreens' market pharmacy supervisors in Florida on July 29, 2010, with the admonition that they "*look at stores on the bottom end .... We need to make sure we aren't turning legitimate scripts away. Please reinforce.*" A corporate market director of pharmacy operations did reinforce this message to Florida market pharmacy supervisors, highlighting that their "*busiest store in Florida*" was filling almost 18 oxycodone prescriptions per day, yet "*We also have stores doing about 1 a day. Are we turning away good customers?*"

    b. At roughly the same time as Walgreens' supervisors were urging its Florida pharmacies to increase their oxycodone sales, Florida enacted new laws to combat the prescription drug abuse problem, particularly the devastating effects of oxycodone and other abused drugs dispensed directly from rogue pain clinics, commonly known as "pill mills." These new laws went into effect on October 1, 2010 and severely restricted the ability of pain clinics and physicians to dispense controlled substances directly from the clinics. The purpose of these legislative changes was to stem the overwhelming tide of controlled substances being

diverted from pill mills and into illicit channels for sale and recreational abuse. As a result, Florida pharmacies and the distributors who served them knew or should have known that starting in late 2010, there would be a significant increase in requests to dispense pursuant to prescriptions issued by physicians associated with the pain clinics.

c. Walgreens store # 06997 in Oviedo, Florida, was ranked 444th on the above-referenced Walgreens' ranking of oxycodone sales generated at its Florida retail pharmacies, filling on average only 4 oxycodone prescriptions per day in June 2010. DEA tracks pharmacy activity not by prescriptions but by dosage units of a particular drug purchased by the pharmacy for retail sales. In 2010, the national average for oxycodone sales to retail pharmacies was 70,395 dosage units per year, or about 5,866 dosage units per month. This store's oxycodone sales began to increase drastically, as shown by the fact that in June 2010, Walgreens store #06997 purchased just 6,600 dosage units of oxycodone products. One year later, in June 2011, this same pharmacy purchased 169,700 dosage units of oxycodone.

d. Oviedo is a town of about 34,000 people and is home to two Walgreens retail pharmacies. Beginning in late 2010, these two pharmacies became the site of multiple arrests by the local police for drug offenses. The local Chief of Police began writing letters to the pharmacies after each arrest stemming from prescriptions they filled. These letters informed the pharmacy of the circumstances of the arrest and that the dispensed drugs were not being used for treatment. They further provided the pharmacy with the name and date of birth not only of the person whose prescription they filled, but also of others associated with the illegal distribution of the dispensed drugs. These letters then concluded with a request for the pharmacy's help in "dealing with the prescription medication epidemic" by soliciting a commitment to stop further incidents.

e. The Oviedo Police Chief's concerns reached the highest levels of Walgreens' Loss Prevention Operations, with the Director of Divisional Loss Prevention noting in an email on January 28, 2011 that "*[e]vidently the Chief of Police is concerned that we are filling too many C2 prescriptions.... From what I've been told, he is referencing 100 plus incidents/arrests in his jurisdiction.*" Walgreens' response was to "*take a look at this market . . . and see if we have an increase in dispensing.*"

f. The Oviedo Police Chief convened a meeting with Walgreens Loss Prevention officials on February 10, 2011, in an effort to further bring awareness of the problems he was seeing at their stores and to brief them on the number of arrests at each location. On March 15, 2011, he sent identical letters to both the Chairman and CEO of Walgreens, asking them for their support and assistance in combating the prescription drug epidemic, informing them that Oviedo "*has seen the parking lots of your stores become a bastion of illegal drug sales and drug use*" where once the prescriptions are filled, "*the drugs are sold, distributed as payment, crushed and snorted, liquefied and injected, or multiple pills swallowed while in the parking lot of your pharmacies.*"

g. Despite being informed at the highest levels of ongoing diversion and drug-related criminal activity directly stemming from dispensing at these pharmacies, and bearing in mind that the average U.S. retail pharmacy in 2011 purchased only 73,000 dosage units of *all formulations* of oxycodone *for the entire year*, the Walgreens corporation, through Respondent, responded to this information about one of its stores by shipping the following quantities of 30 milligram formulation oxycodone to Oviedo store 06997:

(i) February 2011	75,300 dosage units
(ii) March 2011	72,900 dosage units
(iii) April 2011	101,700 dosage units
(iv) May 2011	133,900 dosage units
(v) June 2011	115,200 dosage units
(vi) July 2011	145,300 dosage units

h. Perhaps even more significant than the enormous amount of oxycodone Respondent shipped to this store despite the information provided by the Chief of Police to its pharmacists and most senior leaders, is the fact that the dispensing records for both Oviedo Walgreens pharmacies show that on multiple occasions, they each dispensed additional prescriptions of commonly diverted narcotics to the same individuals who they knew had been previously arrested for drug offenses at their pharmacies. I find this to be a staggering disregard of Walgreens' obligations under the Controlled Substances Act.

17. While the detailed information provided by the Chief of Police put Respondent and its parent company on notice of actual diversion occurring at the two Oviedo pharmacies, Respondent had ample other indications that its pharmacies were direct and significant contributors to the epidemic of prescription drug abuse and diversion in Florida, yet it largely ignored these indicators, at all levels of the corporate structure. An inexhaustive description of some of these indicators are the following:

a. On September 27, 2010, a pharmacist working at Walgreens # 04727 in Ft. Pierce reported to law enforcement that he mistakenly provided an extra 120 dosage units of 15 milligram oxycodone to a customer. When the pharmacist tried to call the customer to request he return the mistakenly dispensed oxycodone, he was told by the customer's girlfriend that the customer was an addict who sells his pills and views the extra oxycodone as a "pot of gold" which he would not return. Despite this incident, Walgreens # 04727 filled several additional oxycodone prescriptions issued to this customer in December 2010 and January 2011.

b. On November 4, 2010, a Walgreens # 04727 pharmacist reported to police that she dispensed a prescription for 60 dosage units of oxycodone 15mg to a twenty-four year old male who she then witnessed transfer the drugs to a female in the store. The female entered the pharmacy restroom, leaving behind evidence indicating she had smoked the oxycodone. Despite this incident, Walgreens # 04727 continued to fill the same customer's oxycodone and alprazolam prescriptions on several occasions in November and December 2010 and January 2011.

c. On December 21, 2010, a pharmacist employed by Walgreens Pharmacy # 3629 in Hudson, Florida reported to the Pasco County (Florida) Sheriff's Office that an individual had attempted to fill a prescription for 270 dosage units of thirty milligram oxycodone, but ran from the pharmacy after learning the pharmacy had contacted law enforcement, suspecting the prescription was a forgery. Despite this incident, the same pharmacy that reported this customer to the Sheriff's Office in December continued to fill the same customer's oxycodone prescriptions in February, March, April, May and October of 2011.

18. On or about March 2011, corporate officials at Walgreens headquarters in Illinois initiated a Florida pharmacy store review initially entitled "Focus on Profit" and later changed to "Focus on Compliance." The purpose of this review was to address the "significant increase in the number of [Schedule II controlled substance] prescriptions we are filling in [Florida]" after the October 2010 change in Florida law regarding pain clinics. The initial pilot survey asked the following questions, amongst others: "Do pain management clinic patients come all at once or in a steady stream?" and "Do you see an increase in pain management prescriptions on the day the warehouse order is received?" On May 17, 2011, in an email with the subject heading "Florida Focus on Profit," a Walgreen Co. corporate attorney reviewed the survey and regarding these two questions, stated "*If these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance.*" The surveys that ultimately were used in the Focus on Compliance initiative did not contain those questions. By omitting these questions in order to avoid gathering information pertinent to whether or not pain clinic patients were engaged in diversion, the Walgreens Corporation and Respondent as a corporate subsidiary, ignored its statutory and regulatory obligation to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. *See* 21 U.S.C. § 823(b) and (e).

19. Apparently as part of this "Focus On Compliance," Walgreens sought to develop and implement "Oxycodone Action Plans" within its districts in Florida in an attempt to reduce the volume of oxycodone dispensing on behalf of pain clinics. For store # 3629 in Hudson, the plan devised by District Pharmacy and Loss Prevention supervisors in a memo dated August 23, 2011 included *"contacting the Jupiter warehouse and designating order limits for Oxycodone."* The plan, effective immediately, was to "limit" the Hudson store to orders of no more than 100 bottles of 100 count 30 milligram oxycodone. Notwithstanding the memo and the plan to limit store #3629's purchases to no more than 100 bottles, Respondent subsequently

shipped the following orders to store 3629:

Date	Bottles	Dosage Units
09/26/11	331	33,100
10/10/11	371	37,100
11/29/11	200	20,000
12/06/11	113	11,300
12/13/11	150	15,000

Respondent's inability to enforce a very simple, modest limitation on this one pharmacy is further evidence of its failure to maintain effective controls against diversion, even in the rare instance when it tried to do so.

20. In mid to late 2011 and continuing into 2012, Walgreens undertook to reduce the volume of oxycodone dispensing at its high-volume pharmacies and in some cases, did, in fact, achieve a relatively significant reduction in Schedule II dispensing at these stores. Additionally, in late May, 2012, approximately seven weeks after Administrative Inspection Warrants were served on six Walgreens retail pharmacies and Respondent, Walgreens suspended dispensing of Schedule II drugs as well as Alprazolam and Carisoprodol at these six pharmacies and two others. In my assessment of the imminent danger posed by Respondent's continued registration, I have considered these remedial measures, as well as Walgreens' claims that it continues to revise its suspicious order reporting system to prevent the excesses that occurred in 2010 and 2011. In my judgment, and in the exercise of the discretion afforded me by 21 U.S.C. § 824(d), the danger posed by Respondent's continued registration is only slightly mitigated by the dispensing restrictions enacted at these eight pharmacies.

21. To reiterate, my concerns with Respondent's distribution practices are not limited to the six Walgreens pharmacies discussed herein. Respondent distributes to over 800 other retail pharmacies in Florida alone, many of which dispense oxycodone in amounts far in excess of the U.S. and Florida averages and which also experienced dramatic increases in their distribution of oxycodone from at least 2009 to the present. No fewer than 43 Walgreens pharmacies in Florida purchased in excess of 500,000 dosage units of oxycodone in 2011, despite a national average of approximately 74,000 dosage units for all U.S. pharmacies and an average of approximately 110,00 dosage units for all Florida Walgreens pharmacies. Florida remains the epicenter of this country's prescription drug abuse problem and notwithstanding the cessation of Schedule II dispensing at eight of its retail customers, Respondent remains the top distributor of the most dangerous prescription drugs in Florida, and still has not made a single suspicious order report in calendar year 2012.

22. Through May of this year, Respondent's customers included 44 Walgreens retail pharmacies on the list of the 100 top oxycodone purchasing pharmacies in Florida.[2] Respondent continues to distribute large amounts of oxycodone while it appears to continue to misunderstand or ignore its obligation to maintain effective controls against diversion by reporting suspicious orders and conducting due diligence on its customer stores to verify the legitimacy of their orders. Thus, the fact that Walgreens stopped selling Schedule II controlled substances to a handful of retail pharmacies – virtually all of which Walgreens also knew were themselves under DEA investigation at the time Walgreens stopped distributing to these pharmacies – does little to mollify my concerns about the danger posed by Respondent's continued operation. The nature and significance of the problems revealed by DEA's investigation indicate that Respondent's anti-diversion measures are inadequate generally; the problems do not appear to be limited to the pharmacies discussed herein. Consequently, I believe that Respondent's continued operation poses an imminent danger to public health and safety.

23. Voluntary dispensing restrictions enacted either in anticipation of, or in reaction to regulatory action, do not indicate to me that Respondent and its parent company have recognized and adequately reformed the systemic shortcomings discussed herein. On the contrary, when a company undertakes to survey its stores for regulatory compliance, then selectively edits that survey for the explicit purpose of avoiding evidence of its own non-compliance, as Walgreens apparently did in May 2011, claims of effective remedial measures have less credibility. I gave significant weight to the fact that Walgreens appears to have deliberately structured certain of its anti-diversion measures to avoid learning about and/or documenting evidence consistent with diversion. At best, I regard this as deliberate indifference on Walgreens' part as to its obligations as a DEA registrant.

24. My confidence in Walgreens' remedial measures is lessened further by the fact that this manipulation of the compliance survey occurred just one month after Walgreens entered into a nationwide Memorandum of Agreement (MOA) with DEA to resolve an Order to Show Cause issued to a San Diego Walgreens pharmacy based on allegations of unlawful dispensing. Walgreens pledged in this MOA to enact a compliance program at all of its retail pharmacies to detect and prevent diversion of controlled substances and to implement and maintain policies and procedures to ensure that prescriptions for controlled substances are only dispensed to authorized individuals pursuant to federal and state law and regulations. Walgreens' effort to enact such a program in Florida appears to have been, in part, intentionally skewed to avoid actually detecting certain evidence of possible diversion. That Walgreens would actively seek to avoid documenting evidence of possible diversion in its "Focus on Compliance" in Florida immediately after entering this MOA, further contributes to my preliminary finding that Respondent's continued registration during

[2] By way of comparison, only two other national or regional chain pharmacies have stores on this list, one of which has four stores in the top 100, while the other has three.

the pendency of this proceeding constitutes an imminent danger to the public health and safety.

IN view of the foregoing, and based on information before the Agency as of the issuance of this notice, it is my preliminary finding pursuant to 21 U.S.C. §§ 823(f) and 824(a)(4), that Walgreens' continued registration is inconsistent with the public interest. Under the summarized facts and circumstances described herein, it is also my preliminary finding, significantly in light of the rampant and deadly problem of prescription controlled substance abuse in Florida, that Respondent's continued registration while these proceedings are pending constitutes an imminent danger to the public health and safety. *See* 21 U.S.C. § 824(d). Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration RW0277752 is hereby suspended, effective immediately. Such suspension shall remain in effect until a final determination is reached in these proceedings.[3]

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that Walgreens possesses pursuant to the registration which I have herein suspended. The said Agents and Investigators are also directed to take into their possession Walgreens's DEA Certificate of Registration RW0277752 and any unused order forms.

THE following procedures are available to you in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Walgreens may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Walgreens fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Walgreens may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).

3. Should Walgreens decline to file a request for a hearing or, should Walgreens request a hearing and then fail to appear at the designated hearing, Walgreens shall be deemed to have waived the right to a hearing and the DEA may cancel

[3] I have primarily addressed Schedule II controlled substances based on Walgreens' representations that Respondent no longer distributes controlled substances other than Schedule II. This should not be construed as an indication that DEA has concluded that Respondent's distribution practices relating to non-schedule II controlled substances conform to all applicable requirements and obligations. To the contrary, many of the problematic distribution practices noted herein would raise imminent danger concerns with respect to non-Schedule II controlled substances if Respondent were to continue to distribute them.

such hearing, and I may enter my final order in this matter without a hearing based upon the evidence presented to me. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation, 8701 Morrissette Drive, Springfield, VA 22152.

Michele M. Leonhart
Administrator
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges
Scott Lawson, Counsel for the Government
Jonathan Novak, Counsel for the Government

REQUEST FOR HEARING

Any person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

DEA Headquarters
Office of the Administrative Law Judges
Hearing Clerk
8701 Morrissette Drive
Springfield, Virginia 22152

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

(A) [State with particularity the interest of the person in the proceeding.]

(B) [State with particularity of the objections or issues, if any concerning which the person desires to be heard.]

(C) [State briefly the position of the person with regard to the particular objections or issues.]

(D) [Name (either registrant, applicant, or attorney), address (including street address, city, state, and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant or attorney]

Note: Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.

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UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF WALGREEN, CO.	DOCKET NO. 13-01 ADMINISTRATIVE LAW JUDGE JOHN J. MULROONEY, II

GOVERNMENT'S PREHEARING STATEMENT

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Date: October 31, 2012

Pursuant to the October 15, 2012 Order for Prehearing Statements, as modified by the October 18, 2012 Order Granting the Respondent's Motion For a Continuance and Amending the Order for Prehearing Statements, the United States Department of Justice, Drug Enforcement Administration (DEA or Government), hereby submits its Prehearing Statement.[1]

I. ISSUE

Whether DEA should revoke DEA Certificate of Registration RW0277752 issued to Walgreen Co. ("Respondent"), pursuant to 21 U.S.C. §§ 824(a)(4) and 823(b) and (e) and deny any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. § 823(b) and (e).

II. REQUESTED RELIEF

The Government requests revocation of Respondent's DEA Certificate of Registration RW0277752.

III. PROPOSED STIPULATIONS OF FACT[2]

1. Respondent is registered with DEA as a distributor in Schedules II-V under DEA Registration RW0277752 at 15998 Walgreens Drive, Jupiter, Florida 33478.

2. DEA Registration Number RW0277752 expires by its terms on May 31, 2013.

IV. PROPOSED WITNESSES[3]

1. Joseph Rannazzisi
   Deputy Assistant Administrator for Diversion Control
   DEA Headquarters
   8701 Morrissette Drive

[1] The Government is filing separately a Motion For an Extension of Time to file this Prehearing Statement, which was originally due on October 29, 2012. The Government was unable to file by this date due to Hurricane Sandy and the resulting closure of the federal government on October 29 and 30, 2012.

[2] The Government anticipates discussing additional stipulations with Respondent.

[3] At this time the Government has not noticed an expert witness. The Government requests the opportunity to supplement its intended witnesses and testimony if it determines that such an expert is necessary in the presentation of its case, and particularly, if Respondent intends to utilize an expert witness.

Springfield, Virginia 22152

2. Susan Langston
Diversion Program Manager
DEA Miami Field Division
2100 North Commerce Parkway
Weston, Florida 33326

3. Kyle Wright
Chief, Targeting and Analysis Unit
DEA Headquarters
8701 Morrissette Drive
Springfield, Virginia 22152

4. Donna Richards
Acting Diversion Group Supervisor
DEA Miami Field Division
2100 North Commerce Parkway
Weston, Florida 33326

5. Phyllis Garrett
Diversion Investigator
DEA Miami Field Division
2100 North Commerce Parkway
Weston, Florida 33326

6. Chief Jeffrey Chudnow
Oviedo Police Department
300 Alexandria Boulevard
Oviedo, Florida 32766

7. Robert Varno
Walgreen Co.
15998 Walgreens Drive
Jupiter, Florida 33478

8. Christine Atwell
Walgreen Co.
15998 Walgreens Drive
Jupiter, Florida 33478

9. Kathy L. Federico
Diversion Group Supervisor
Milwaukee District Office
4725 West Electric Avenue
West Milwaukee, Wisconsin 53219

10. George Corripio
Pharmacist
Walgreen Co. Store # 5079
2423 Orange Ave.
Ft. Pierce, Florida

11. Edward J. Lanzetti
Walgreen Co. Market Loss Prevention Director
7003 Presidents Dr., #250
Orlando, Florida 32809

V. SUMMARY OF TESTIMONY

1. Deputy Assistant Administrator Joseph Rannazzisi

Deputy Assistant Administrator Rannazzisi will describe his background, education and training as a DEA Deputy Assistant Administrator, a law enforcement officer, and a licensed pharmacist. He will further testify substantially as follows:

Prescription drug abuse occurs in the United States at an alarming rate. The 2010 National Survey on Drug Use and Health reveals that approximately 7 million Americans abuse controlled substance pharmaceuticals for non-medical purposes. Second only to marijuana, controlled substance prescription drugs are abused by more people than cocaine, heroin, hallucinogens and inhalants combined. Of all prescription drugs, narcotic pain relievers such as oxycodone, hydrocodone, and oxymorphone are abused most frequently. Each year, roughly 5.1 million people abuse narcotic pain relievers in the United States.

Beginning in late 2008 and continuing to the present, there has been a significant rise in the number of rogue pain clinics whose complicit doctors were initially permitted to dispense millions of dosage units of oxycodone and other abused drugs directly from the clinics. Florida is the epicenter for these illegal pain clinics. DEA, State and local law enforcement investigations reveal that thousands of drug seekers flock to these Florida-based pain clinics to obtain their supply of oxycodone, and other controlled substances such as alprazolam, which is

in turn illegally redistributed in states along the entire east coast and Midwest.

The illicit pain clinics, the pharmacies that fill their scripts, and the wholesale distributors who supply pharmacies without appropriate due diligence (including Respondent), have caused, and continue to cause, millions of dosage units of oxycodone and other controlled substances to be diverted, posing a serious threat to the public health and safety. According to the Florida Medical Examiner's Office, they have seen a 345.9% increase in the number of overdose deaths associated with oxycodone between 2005 and 2010. For 2010, their data showed that approximately 4,091 persons died in Florida alone from an overdose caused by just five drugs: methadone, oxycodone, hydrocodone, benzodiazepines, or morphine.

Furthermore, the abuse of prescription drugs is not isolated to just one drug. Abusers and addicts routinely abuse prescription drugs in combination with one another to enhance the effects. This activity significantly increases the risk of potential harm to the individual. This combination is often referred to as a "cocktail" of hydrocodone or oxycodone used in combination with alprazolam (a benzodiazepine) and carisoprodol. According to the Florida Medical Examiner's Office, they have seen a 127% increase in the number of deaths associated with benzodiazepines in the State of Florida between 2005 and 2010.

On July 1, 2011, the State Health Officer and Surgeon General, Dr. Frank Farmer issued a statewide public health emergency declaration in response to the ongoing problem of prescription drug abuse and diversion in Florida. The press release accompanying this emergency declaration noted more oxycodone is dispensed in the state of Florida than in all remaining states combined. It further stated that in 2010, "98 of the top 100 doctors dispensing Oxycodone nationally were in Florida"; and that "126 million oxycodone pills were dispensed through the top 100 dispensing pharmacies in Florida".

Following changes in Florida law aimed at curbing the problematic dispensing direct from the pain clinics, drug abusers have found other ways to obtain oxycodone and other "cocktail" drugs. Rather than dispensing the drugs directly to "patients," pain clinics and complicit doctors are now forced to write prescriptions for oxycodone and other abused drugs. Drug abusers wanting their prescriptions filled must take their prescriptions to a retail pharmacy. The result was that law enforcement saw immediate and significant increases in the volume of oxycodone dispensed from retail pharmacies across the state of Florida. Retail pharmacies are generally supplied by a DEA-registered wholesale distributor. The doctors and clinics that prescribe oxycodone inappropriately, the pharmacies that dispense their prescriptions, and the wholesale distributors who supply them have caused, and continue to cause, millions of dosage units of oxycodone to be diverted for unlawful use thereby creating an imminent threat to the public health and safety.

Deputy Assistant Administrator Rannazzisi will authenticate and describe the purpose behind three letters sent by DEA to all distributors and manufacturers, including Respondent, on September 27, 2006, February 7, 2007, and December 27, 2007. These letters explained to distributor registrants their obligations to maintain effective controls against diversion and report suspicious orders as part of their duties within the closed system established by the Controlled Substances Act (CSA). He will describe the purpose of the suspicious order requirement of 21 C.F.R. §1301.74(b) and its relationship to the statutory obligation of all distributors to maintain effective controls against diversion of controlled substances pursuant to 21 U.S.C. §§ 823(b)(1) & 823(d)(1). Consistent with the guidance of these letters, he will describe a distributor's obligation to devise and implement an effective system to identify suspicious orders and the obligation to report suspicious orders to DEA as they are discovered. He will further testify that

a distributor has an obligation under the statutory and regulatory scheme to determine the legitimacy of any order it identifies as suspicious prior to fulfilling that order.

He will further testify that distributors have a statutory obligation to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific and industrial channels and that the exercise of this obligation requires a distributor to confirm the legitimacy of all orders prior to filling. He will describe the general ways in which distributors commonly perform and document this due diligence and will describe common indicators of diversion that all distributors should be alert to at their customer pharmacies. He will testify that these obligations apply equally to distributor registrants regardless of whether their customers are independent or chain pharmacies and regardless of whether the distributor and its customers are under common ownership.

Based on the evidence of its' suspicious order program provided by Respondent, he will testify that the Walgreen Co.'s suspicious order program fails to comply with Respondent's obligations under 21 C.F.R. §1301.74(b). He will testify that the "Suspicious Control Drug Orders" report provided to DEA on Respondent's behalf monthly by Walgreen Co. corporate headquarters constitutes nothing more than a monthly report of completed transactions and therefore does not meet the regulatory requirement to report suspicious orders as discovered, as is spelled out in his December 27, 2007 letter to Respondent. In other words, despite the title attached to these compilations of completed transactions, he will testify that they are not suspicious order reports under the regulation. Furthermore, he will testify that based on the documents provided by Walgreen Co., Respondent appears to have conducted little to no investigation or analysis of the orders it reported as suspicious prior to completing the sale of these orders, despite the fact that on a single day, many of these orders greatly exceeded the

monthly threshold established by Respondent for reporting orders of a particular controlled substance as suspicious.

Moreover, he will testify that the monthly reports of completed "suspicious" transactions reported by Respondent were misleading in that they did not report each order received and shipped by Respondent, but instead aggregated the orders shipped on any given day. Further, he will testify that the reports made by Respondent are flawed in that they include all orders for a particular controlled substance shipped to a particular pharmacy in a given month and do not indicate which of these orders are being reported as suspicious. He will testify that based on the foregoing, Respondent did not make a single proper suspicious order report, despite a history of supplying its customers, particularly but not limited to its Florida retail pharmacies, incredibly large amounts of the most commonly abused and diverted controlled substances.

He will testify regarding the Walgreen Co.'s current suspicious order policy, applicable to all of its distribution centers, including Respondent, which indicates that as of January 1, 2012, the company will no longer make suspicious order reports as a result of a system that supposedly prevents shipment of any suspicious orders. He will testify that such a policy evidences a misunderstanding of the suspicious order reporting requirement, which is triggered by suspicious orders for controlled substances, not only when such an order is actually shipped. He will testify that this operating statement on behalf of Respondent is further evidence of the lack of an appropriate system under 21 C.F.R. § 1301.74(b) and is indicative of ineffective controls against the diversion of controlled substances.

Finally, he will discuss the additional requirements imposed upon the Walgreen Co's operation of its retail pharmacies by the Memorandum of Agreement entered into between DEA and Walgreen Co. in April, 2011.

2. Susan Langston, Diversion Program Manager ("DPM"), Miami Field Division (MFD)

DPM Langston will testify to her background, education and training as a DEA Diversion Investigator, Diversion Group Supervisor, and Diversion Program Manager. She will testify substantially as follows:

Since at least 2009, the State of Florida has been the epicenter of a notorious, well-documented epidemic of prescription drug abuse. In July 2011, the Florida Surgeon General declared a Public Health Emergency based on the prescription pill epidemic which results in an average of seven overdose deaths per day in Florida. The controlled substances most commonly associated with this epidemic are typically prescribed at unscrupulous pain clinics by physicians acting outside the usual course of professional practice and include Schedule II pain relievers, such as oxycodone (which is highly addictive and known to be highly abused an diverted in the State of Florida); Schedule IV benzodiazepines, such as alprazolam; and Schedule IV muscle relaxers, such as carisoprodol. Frequently, these controlled substances are prescribed in large amounts and in combination with each other as "cocktails" popular with drug seeking individuals. According to the 2010 Florida Medical Examiner's Commission Drug Report, the drug that caused the most deaths in the State of Florida for 2010 was oxycodone (1,516 deaths), followed by benzodiazepines (1,304 deaths of which 981 were caused by alprazolam). DPM Langston will testify regarding changes to Florida law aimed at curbing this problem that restricted the ability of practitioners to dispense controlled substances to patients and how the epidemic of controlled substance drug abuse and diversion has now shifted to pharmacies.

DPM Langston will explain why Respondent and 6 of its retail pharmacy customers were targeted for investigation. She will testify about statistical information compiled by DEA's

ARCOS ("Automation of Reports and Consolidated Orders System") unit, identifying the largest distributors of oxycodone and related controlled substances in Florida, as well as the largest retail pharmacy purchasers of these substances in Florida from 2008 to the present. She will introduce charts showing these pharmacies' oxycodone purchases from at least 2008 to the present and describe why the size and frequency of these purchases should have created suspicion within Walgreen Co. and Respondent that these pharmacies were diverting controlled substances.

She will testify that on August 19, 2011, DEA met with Walgreens personnel at the DEA MFD offices in Weston, Florida to apprise them of relevant ARCOS information about Walgreens' sales of oxycodone in Florida. Present from Walgreens were Dwayne Pinon (corporate in-house counsel), Ed Forbes (Market Loss Prevention Director), Wesley Rohn (Pharmacy District Supervisor), Joan Bustelo (Pharmacy District Supervisor), Anne-Marie Aldrich (Pharmacy District Supervisor), Cesar Cedeno (Pharmacy District Supervisor), Georgia Lehoczky (Market Pharmacy Director), Robert Espinosa (Pharmacy Supervisor), Lakeisha Axem (Pharmacy Supervisor), Sandra Vazquez (Pharmacy Supervisor) and Susan Thompson, Loss Prevention Manager. She will testify that the Walgreens officials at this meeting were told, amongst other things, that 20 Florida Walgreens pharmacies were in the top 300 of oxycodone purchasers in the United States for the first half of 2011 and within the State of Florida over the same time frame, 100 of the top 300 pharmacy oxycodone purchasers were Walgreens retail pharmacies. Moreover, Florida Walgreens pharmacies purchased more than double the average amount of oxycodone purchased by Florida pharmacies.

DPM Langston will discuss the "Suspicious Control Drug Order" reports received by DEA from Walgreens. She will testify that these reports were sent to DEA from Walgreens Loss

Prevention officials at corporate headquarters in Illinois on behalf of the Jupiter Distribution Center. She will discuss the contents of these reports, how frequently they were submitted, and what DEA was able to glean from an examination of these reports. DPM Langston will testify that the reports were not in compliance with DEA's clear edict regarding what should and should not be contained in a suspicious order report. She will also testify that in 2012, DEA has not received a single suspicious order report from either Walgreens Corporate Headquarters or from the Jupiter distribution center.

DPM Langston will discuss the execution of Administrative Inspection Warrants (AIW), on April 4, 2012 at six Walgreens pharmacies and Respondent, along with the service of an administrative subpoena for additional records from Respondent, the six pharmacies, and their corporate headquarters. She will testify regarding the meaning of the subpoena's request for "due diligence" files and her efforts to communicate this concept to Respondent. Further, she will testify to the types of information traditionally found within such files maintained by distributor registrants and the traditional steps distributors undertake to monitor their customers and assess whether or not they are involved in diversion.

She will also introduce emails produced by Walgreens in response to the subpoena, in which the corporation urges its Florida pharmacy supervisors to increase their oxycodone sales and she will discuss other emails indicating that Walgreens' officials were aware of excessive dispensing at some of these 6 pharmacies, all of whom received their Schedule II controlled substances from Respondent. She will discuss Walgreen Co.'s dispensing guidelines for its Florida pharmacies and the development and results of a survey entitled "Focus on Compliance", the purpose of which was to assess the scope of the diversion problem at Walgreen's Florida pharmacies.

DPM Langston will testify about multiple specific suspicious orders placed by the six related Walgreens pharmacies during 2011, which were filled despite their suspicious nature and without Respondent conducting any due diligence to ensure these orders were not being diverted. DPM Langston will discuss the specific order dates, the objective suspicious factors related to the orders, such as size and quantity, as well as the subjective factors creating a situation in which Walgreens knew or should have known that the orders were suspicious and that these pharmacies' dispensing practices posed an unreasonable risk of diversion. DPM Langston will discuss due diligence steps that could have and should have been taken before the distribution center shipped the orders. She will also describe numerous "red flags" of diversion evident from a review of the records available to Respondent from the individual pharmacies it served.

3. Office of Diversion Control, Unit Chief Kyle Wright

Mr. Wright will testify to his background, education and training as the Targeting and Analysis Unit Chief in the Office of Diversion Control. He will further testify as follows:

Mr. Wright will testify regarding the Automation of Reports and Consolidated Orders System ("ARCOS") data regarding Respondent's sales of controlled substances. He will testify to the background of ARCOS, its purpose, the information ARCOS contains, and how the information is used by DEA to identify potential diversion of controlled substances. He will testify that he used ARCOS information to conduct an analysis of Respondent's sales of controlled substances. Specifically, he will testify with respect to the ARCOS information for Respondent's top six retail pharmacy customers. Wright will further authenticate charts showing comparative levels of controlled substance purchases among Respondent's various retail chain customers from 2008 to the present, to include the average oxycodone purchasing by all of Respondent's customers; its Florida customers; and the six targeted Walgreens pharmacies.

Wright will further testify to the importance of accurate and complete reporting to ARCOS and will testify that a distributor who reports in a manner that consolidates multiple orders under separate DEA Forms 222 into a single Form 222 is not making a complete and accurate report. Wright will authenticate documents showing Respondent's ARCOS reporting on a number of occasions and compare this reporting to the actual sales information from the source documents.

4. Acting Group Supervisor ("A/GS") Donna Richards

A/GS Donna Richards will testify to her background, education and training as a DEA Diversion Investigator and Group Supervisor. She will testify substantially as follows:

A/GS Richards conducted a thorough review of the materials provided by Walgreens in response to the administrative subpoena issued by DEA. She will testify that her review of these documents produced no actual showing of any due diligence exercised by Respondent to verify the legitimacy of their increasingly frequent and large orders for highly abused controlled substances. The one exception A/GS Richards will note are several emails from the Jupiter distribution center CII Function Manager, Christine Atwell, questioning the size and frequency of orders from particular pharmacies. Richards will testify that despite Respondent's apparent concern about the orders it was fulfilling on behalf of these pharmacies, Respondent continued to ship suspiciously large quantities of controlled substances to these pharmacies and did not properly report any of the orders that Atwell questioned, or that were subsequently shipped to these pharmacies as suspicious. Richards will testify that based on the Walgreen Co.'s response to DEA's request for due diligence files, Respondent filled these orders without adequately resolving Atwell's concerns or otherwise conducting any investigation of these orders to determine that they were not being diverted.

Richards will further testify about several particular incidents occurring at Respondent's customer pharmacies that should have increased Respondent's scrutiny of these customers, all of whom were already purchasing unusually large quantities of the most commonly abused and diverted controlled substances. One of these incidents occurred in December 2010, at Walgreens store 03629 in Hudson, Florida. An individual attempted to fill a prescription for 270 thirty milligram oxycodone tablets but abruptly left the pharmacy without the narcotics he was seeking after apparently learning that pharmacy personnel, who had reviewed the prescription and suspected it was a forgery, had contacted law enforcement. Despite being put on notice that this customer was likely diverting, Walgreens 03629 continued filling prescriptions for the customer through October 2011. All of the prescriptions were for oxycodone, hydromorphone and/or alprazolam, were paid for in cash and issued by physicians located a significant distance from Walgreens 03629. She will further testify that efforts by Walgreens to impose order limits on this particular store in light of its problematic dispensing did not succeed.

Similarly, Richards will testify that on September 27, 2010, a pharmacist at Walgreens store 04727 in Ft. Pierce, Florida, reported to local law enforcement that he mistakenly provided an extra 120 dosage units of oxycodone 15mg to a customer. The pharmacist stated that when he spoke to the customer's girlfriend to request the return of the oxycodone, the girlfriend said that the customer was an addict who sold his pills and viewed the extra prescription as a "pot of gold." Despite this incident, Walgreens 04727 continued to fill this customer's prescriptions for oxycodone 15mg and oxycodone 30mg on December 30, 2010 and January 26, 2011.

On November 4, 2010, a Walgreens 04727 pharmacist reported to local law enforcement that she dispensed a prescription for 60 dosage units of oxycodone 15mg to a customer. The pharmacist witnessed the customer hand the prescription to a female in the store. The female

entered the restroom with the prescription and upon leaving the restroom, left evidence (aluminum foil with burn marks and pill residue) indicating that she had used the oxycodone in an illicit manner. Despite this incident, Walgreens 04727 continued to fill the customer's oxycodone and alprazolam prescriptions on November 30, 2010, December 13, 2010, December 27, 2010, and January 24, 2011. Additionally, on two of these occasions, the pharmacist noted on the prescription that the customer did not have identification and/or a passport.

On October 28, 2011, the Sheriff of St. Lucie County notified Walgreens 04727 by letter that it needed to take action to stem the tide of prescription drug diversion. St. Lucie County Sheriff Ken Mascara requested Walgreens 04727's "help in dealing the with prescription painkiller epidemic" in St. Lucie County and Florida by "closely scrutinizing" prescriptions for Schedule II narcotics, written by out-of-town physicians and/or written for out-of town individuals. Nevertheless, Walgreens 04727 continued its practice of filling numerous opiate/opioid prescriptions issued by out-of-town physicians through early 2012. Several of these out-of town physicians subsequently surrendered their registrations for cause and/or were subject to state action for their conduct involving controlled substances prescriptions.

She will also provide additional examples of orders for controlled substances received by Respondent that, given the information available to the Walgreen Co., including the above-related police incidents and the below-summarized testimony of Oviedo Police Chief Chudnow, should have been considered suspicious. She will provide testimony that despite clear "red flags" of diversion at some of its customer pharmacies, the distribution center shipped suspicious orders to these pharmacies without executing any due diligence to resolve the potential for diversion.

5. Diversion Investigator ("DI") Phyllis Garrett

DI Phyllis Garrett will testify to her background, education and training as a DEA Diversion Investigator. She will testify as follows:

A review of the ARCOS information reported by the Jupiter distribution center to DEA revealed failures to report complete and accurate information to ARCOS. Specifically, DI Garrett will point to examples where Walgreens reported a single ordered quantity of Schedule II controlled substances, while the actual amounts were ordered over several DEA 222 forms, amounting to several separate transactions instead of one. DI Garrett's testimony, along with that of Kyle Wright, will be used to admit documents showing these failures to report completely and accurately.

She will introduce evidence of particular shipments of 30mg oxycodone to the six pharmacies named in the Order to Show Cause and will describe the characteristics of these orders that should have triggered both a suspicious order report and additional investigation from Respondent prior to shipping.

6. Oviedo Chief of Police Jeffrey Chudnow

Chief Chudnow will testify about his background, training and experience as a police officer and as the Chief of Police for Oveido, Florida. Chief Chudnow will testify about the very tangible effects that the diversion of controlled substances has had on the city of Oveido, as evidenced by increases in, among other things, crime rates and overdoses. Chief Chudnow will testify about his department's knowledge of Walgreens 06997, as well as another Walgreens within the city limits, as centers for illicit controlled substance sales and use.

The Oveido Police Department (OPD) made numerous arrests for illegal distribution of

controlled substances in 2010 and 2011 related to controlled substances dispensed at the two Walgreens pharmacies, with many of the illicit transactions preceding these arrests occurring in the parking lots of the stores. Chief Chudnow will testify that it was his practice following one of these arrests to send a letter to the pharmacy which dispensed the controlled substance being diverted, notifying them of the details and asking for the pharmacy's assistance in preventing future diversion. Chief Chudnow sent dozens of these letters, at least five of which will be offered into evidence because, as noted in the ISO, Walgreens Store 06997 continued to dispense to some of these individuals even after being notified of their arrest.[4]

On February 10, 2011, Chief Chudnow met with Ed Lanzetti, Walgreens Market Loss Prevention Director, and another Walgreens official. At the meeting, Chief Chudnow presented Mr. Lanzetti with numerous statistics and facts regarding controlled substance arrests related to Walgreens' two Oveido pharmacies. These statistics included numbers and types of drug-related arrests, types of controlled substances seized per arrest, and statistics showing the names of doctors whose prescriptions were related to diversion arrests. Despite being given this information, Walgreens 06997 continued to fill prescriptions for these associated doctors subsequent to the February meeting with Chief Chudnow.

On March 15, 2011, Chief Chudnow sent letters to Alan G. McNally, Chairman of Walgreens Corporation and to Gregory D. Wasson, President and CEO of Walgreens Corporation, informing them about the numerous controlled substance arrests taking place at the Oveido Walgreens pharmacies and the effects on the community of Oveido, and asking for their assistance in stopping these problems. Chief Chudnow never received any response to his request for assistance from anyone at Walgreens Corporation.

[4] DEA will offer the evidence of subsequent dispensing to the subjects of Chudnow's letters through a Diversion Investigator and will specify these individuals and supporting documents in a Supplemental Prehearing Statement, after moving for a protective order concerning the personal information to be disclosed in these exhibits.

7. Robert Varno

Varno will be asked to testify about his experience as Respondent's Distribution Center Manager in Jupiter, Florida from June 2001 until June 2012. Varno will testify about his responsibilities as the manager of the distribution center, including the filling of orders for all of the Walgreens retail pharmacies serviced by the Jupiter distribution center. Varno will be asked to explain the distribution of controlled substances to the Walgreens retail pharmacies, including the use of DEA Form 222 for filling orders for Schedule II controlled substances. Varno will testify regarding his knowledge and use of shipping information reported to ARCOS, as well as Suspicious Order Reports, his understanding of their creation and his use of these reports in managing the distribution center. He will discuss how these reports were received and stored at the distribution center, his utilization of these reports, and how these reports impacted shipping operations at the distribution center. Varno will testify about his training in anti-diversion measures by Walgreen's Headquarters and/or Loss Prevention officials, particularly those portions of his training focusing on Florida's well-known epidemic of prescription drug abuse. He will also testify about his own knowledge of the prescription drug problem in Florida and how that awareness impacted operations at Respondent, particularly with regard to identifying and verifying suspicious orders of commonly abused painkillers.

8. Christine Atwell

Christine Atwell will be asked to testify about her more than six years of experience as the CII Function Manager at the Walgreens distribution center in Jupiter, Florida. Atwell will explain the role of the CII Function Manager as part of the distribution center operations, including her functions while serving in that role. She will explain the system for filling orders for Schedule II controlled substances in place in 2010 and 2011, including the filling of standard

orders, the filling of "PDQ[5]" orders and the filling of orders for a quantity beyond the stock on hand at the distribution center. Atwell will discuss how the Distribution Center handled orders placed directly by pharmacy employees in addition to the automated system. She will testify about the process of reviewing orders for controlled substances received at the distribution center, as well as about the guidance and training she received from Walgreen Co. on how to evaluate special orders. Atwell is expected to testify that she had full approval authority on all special orders placed by pharmacies. She will testify about how the automated system handled DEA Form 222 documentation of orders filled by the distribution center, as well as any controlled substances ordered but not filled by the distribution center.

Atwell will testify regarding her knowledge and use of information reported to ARCOS, as well as Suspicious Order Reports, to include her understanding of their creation and her use of these reports in managing the distribution center's CII functions. She will testify about her training in anti-diversion measures by Walgreen's Headquarters and/or Loss Prevention officials, particularly those portions of this training focusing on Florida's well-known epidemic of prescription drug abuse. She will also testify about her own knowledge of the prescription drug problem in Florida and how that awareness impacted operations at Respondent, particularly with regard to identifying and verifying suspicious orders of commonly abused painkillers.

As the CII Function Manager, Atwell will testify regarding emails she sent to Walgreens corporate personnel, including Barbara Martin and Distribution Center Manager Rob Varno, voicing concerns about the unusual size and frequency of orders being placed by several pharmacies. She will testify about Walgreens response to those concerns and her awareness of any efforts by Walgreens to address the prescription drug problem both nationally and within

[5] PDQ is internal vernacular used by Walgreens for "Pretty Darn Quick," or for orders received daily at the distribution center for fast turnaround outside the regular weekly orders.

Florida.

Atwell will discuss changes to the automated filling systems implemented at the Jupiter Distribution Center in 2012. She will also discuss her understanding of the suspicious order reports produced by Walgreens, including that she has no input into the creation of these reports and she never utilized these reports as part of her role as CII Function Manager at the distribution center. She will testify that during her tenure as the CII Function Manager at the Jupiter distribution center, she has never stopped an order from being filled and distributed. [6]

9. Group Supervisor ("GS") Kathy Federico

GS Federico will testify to her background, education and training as a DEA Group Supervisor. She will testify as follows:

On June 14, 2012, GS Federico, of the DEA Milwaukee District Office, spoke with Dwayne Pinon, in-house corporate counsel for Walgreen, Co., in a telephone interview. During the interview, Pinon stated that Walgreens' prior suspicious order reporting system was based on a formula for Pseudoephedrine reporting in the DEA Chemical Handlers Handbook. Pinon stated that the old system automatically reported any orders for quantities above the algorithm's threshold limit. He stated that DEA had informed Walgreens that this algorithm reporting system was outdated and that Walgreens needed to establish their own system for reporting suspicious orders. Pinon stated that the old reports were not suspicious orders, but were in fact just orders that "bounced off" the old reporting system. Pinon informed Federico that Walgreens had implemented a new system which they hoped to present to DEA at some point. The new system set limits on a pharmacy ordering controlled substances based on their sales history, and

[6] Both Ms. Atwell and Mr. Varno were interviewed by DEA in August, 2012, with counsel for Respondent present. The Government reserves the right to present evidence of their statements through the testimony of DI's Richards and/or Garrett, particularly if either or both do not testify at the hearing.

any order over the set limit would trigger an alert to Walgreens Loss Prevention. Loss Prevention would then resolve the order. Pinon stated that any orders that Loss Prevention could not resolve would be reported to DEA. However, he stated that initial implementation of this new version of the Suspicious Order Monitoring System had produced "thousands" of allegedly suspicious orders, and was thus still being adjusted to produce different results.

10. George Corripio

George Corripio will testify about his thirty-one (31) years of experience as a pharmacist, and his current position as a Walgreen's Staff Pharmacist at Walgreens #5079 at 2423 Orange Avenue, Ft. Pierce, Florida 34950. Corripio will testify about a brief period in 2011 when he worked at Walgreens #4727, also located in Ft. Pierce, Florida. Corripio will testify as follows:

Unlike the customers at The clientele at Walgreens #4727 was "heavy CII traffic," and that "80% of the clientele was oxy[codone]." In his professional opinion, the diagnoses did not match the customers, as most of the clientele were young people and most of the diagnoses were for back pain. He felt that most of the customers were not telling the truth. The customers were young, they seemed to all now each other, and they often appeared to be under the influence. Often the clientele would present "cocktail prescriptions." On one occasion, a female customer presented a prescription for ten opiates, which is the type of prescription dispensed to a patient suffering from terminal illness.

Corripio will testify about his general discomfort at filling oxycodone prescriptions at Walgreens #4727, and about how supervising pharmacist did not seem bothered by the clientele and offered to fill prescriptions for Corripio that he felt uncomfortable filling. She suggested that as long as the pharmacy had a diagnosis code for the prescription, they were fine to fill. When Corripio refused to fill a prescription, the customer would often ask when the female pharmacist

was coming back.

Corripio will testify that in his professional opinion, any reasonable pharmacist and technician would know that something was not right with the situation going on at the pharmacy. Corripio brought the situation to the attention of the local police department to seek help with the problems. Corripio will further testify that he believed his District pharmacy supervisor knew about the dispensing practices at Store # 4727. [7]

11. Edward J. Lanzetti

Mr.Lanzetti will testify about his employment and duties at Walgreens as a Market Loss Prevention Director. He will be asked to describe his knowledge of the prescription drug abuse problem in Florida and about Walgreens' efforts to combat these issues. He will be asked to describe the Loss Prevention program as it pertains to anti-diversion measures and the methods used by Walgreens' Loss Prevention program to detect and prevent diversion at its pharmacies. Lanzetti will be asked about the increases in oxycodone sales at Walgreens pharmacies in 2010. He will also be questioned about his meeting with Chief Jeffrey Chudnow of the Oviedo Police Department, and about any actions taken in response by the Walgreen Corporation.

VI. PROPOSED DOCUMENTS

Exhibit	Description	Approx. # Pages
1.	DEA Certificate of Registration RW0277752 (attached hereto)	1
2.	Sep 27, 2006 Letter from Deputy Asst. Administrator to Respondent	4
3.	Feb 7, 2007 Letter from Deputy Asst. Administrator to Respondent	2

[7] Mr. Corripio was also interviewed by DEA in August, 2012, with counsel for Respondent present. The Government reserves the right to present evidence his statements through the testimony of DI's Richards and/or Garrett, particularly if Corripio does not testify at the hearing.

Exhibit	Description	Approx. # Pages
4.	Dec 27, 2007 Letter from Deputy Asst. Administrator to Respondent	4
5.	2011 Memorandum of Agreement between DEA and Walgreen Co.	7
6.	Florida Declaration of Public Health Emergency	3
7.	HDMA Guidance on Suspicious Order Reporting	16
8.	Walgreen Policy: Handling Suspicious Drug Orders, Revised 2/15/05	1
9.	Walgreen Policy: Handling Suspicious Orders and Loss of Controlled Drugs, Revised 2/15/05	1
10.	Walgreen: Handwritten Revisions to Suspicious Order Policies, undated	2
11.	Walgreen Policy: Handling Suspicious Drug Orders, Revised 04/02/202 (sic)	1
12.	Walgreen Policy: Handling Suspicious Orders and Loss of Controlled Drugs, Revised 04/02/2012	1
13.	"Controlled Substance Threshold" Project P09002, Feb. 2009	18
14.	Jupiter CII Suspicious Control Drug Orders Report with cover letter dated Dec. 30, 2011	1500+ *
15.	Jupiter CII Suspicious Control Drug Orders Report with cover letter dated Nov. 30, 2011	1500+ *
16.	Jupiter CII Suspicious Control Drug Orders Report with cover letter dated Oct. 31, 2011	1500+ *
17.	Jupiter CII Suspicious Control Drug Orders Report with cover letter dated Sep. 30, 2011	1500+ *
18.	Jupiter CII Suspicious Control Drug Orders Report with cover letter dated July 31, 2011	1500+ *
19.	Jupiter CII Suspicious Control Drug Orders Report with cover letter dated May 5, 2011	1500+ *
20.	Chart of Top Oxycodone Dispensing Florida Pharmacies, 2008-2012.	5
21.	Chart of Oxycodone Sales to Selected Walgreens Pharmacies, 2006-2012	7
22.	Chart of Oxycodone Average Sales: US average, Florida average, Walgreens Nationwide Average, Walgreens Florida Average.	2
23.	Chart of Oxycodone 30 mg Orders Shipped to Selected Pharmacies	5

Exhibit	Description	Approx. # Pages
24.	2011 MOA between Walgreens and DEA	7
25.	Chart and Supporting Documents – Inaccurate ARCOS Reporting	10
26.	Excerpts from DEA Pharmacist Manual	5
27.	Chart: Oxycodone Sales Comparisons of Selected Walgreens Pharmacies	4
28.	Oviedo Police Department Letters to Walgreens	10
29.	Walgreen Emails Re: Oxycodone Sales **	2
30.	Walgreens Emails re: pharmacy orders **	15
31.	Walgreens Emails re: Ft. Pierce Pharmacies 4727 & 4391 **	8
32.	Walgreens Email about Oviedo Police Chief **	2
33.	Walgreens Emails re: Focus on Compliance **	25
34.	Walgreens Emails re: Oxycodone Action Plans **	8
35.	Walgreens Emails re: Dispensing Guidelines **	10
36.	Selected DEA Forms 222 From Respondent	25
37.	ARCOS Information Submitted by Respondent for the transactions in Exhibit 33.	5
38.	Police Reports re: individual incidents at selected pharmacies	15

* The Government will seek to only use excerpts from these reports in order to limit the size of each exhibit well below the number of pages contained within the original report.

** Respondent has informed the Government that it will be providing a Bates-stamped replica of the material it originally provided in response to a subpoena without any numeration. Once received, the Government will use these materials to specify exactly which documents are being used and provide a more detailed exhibit list in subsequent filings.

VII. OTHER MATTERS

As this and related matters not currently before the Court are part of an ongoing investigation, the Government requests the opportunity to supplement this Prehearing Statement as necessary with additional witnesses and documentary evidence. There may also be a need to supplement or revise in response to ongoing litigation brought by Respondent in both the Eastern District of Virginia and the Court of Appeals for the District of Columbia.

Pursuant to the Court's Amended Order for Prehearing Statements, the Government's position at this time is that paragraph 20 of the OTSC/ISO is the only portion of the charging document that is *solely* relevant to the Administrator's findings of an imminent danger to the public health and safety. While other portions of the OTSC/ISO also support this finding, they are also relevant to the issues to be determined herein, particularly at this stage of the proceeding, where the Government is not yet aware of the particular defenses to be raised by Respondent.

VIII. POSITION REGARDING HEARING SITUS

At this time, the Government does not request a change of location for the hearing, though this position is subject to clarification of the means and method of securing the presentation of testimony by civilian witnesses located more than 500 miles from the site of the hearing. *See* 21 U.S.C. § 876. This concern would be substantially alleviated should Respondent agree to produce in person any current employee requested in this Prehearing Statement or supplements thereto.

IX. BEST ESTIMATE AS TO TIME REQUIRED TO PRESENT CASE

The Government anticipates requiring no more than four (4) days to present its case-in-chief, exclusive of cross-examination and rebuttal.

Respectfully submitted,

SCOTT LAWSON
JONATHAN P. NOVAK
Attorneys
Diversion & Regulatory Litigation
Office of Chief Counsel

Date: October 31, 2012

CERTIFICATE OF SERVICE

I hereby certify that on the date signed below, I caused the original and two copies of the foregoing **GOVERNMENT'S PREHEARING STATEMENT**, to be hand delivered and faxed to the DEA Office of the Administrative Law Judges, and I caused a copy of the same to be sent, *via e-mail* to counsel for Respondent at the following addresses:

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30.0.12
Date

Signature

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UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF WALGREEN, CO.	DOCKET NO. 13-01 ADMINISTRATIVE LAW JUDGE JOHN J. MULROONEY, II

GOVERNMENT'S SUPPLEMENTAL PREHEARING STATEMENT

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Date: December 7, 2012

Pursuant to the November 20, 2012 Prehearing Ruling, the Government hereby submits its Supplemental Prehearing Statement.

The Government supplements the proposed testimony of its previously disclosed witnesses as follows:

1. **Deputy Assistant Administrator Joseph Rannazzisi**

Both the ISO and the Government's Prehearing Statement refer to three letters issued by Deputy Administrator Rannazzissi. The second of these two letters, dated February 7, 2007, is identical to the first, dated September 27, 2006. The Government therefore will not be referencing the February 7, 2007 letter in its proposed testimony and has removed this document from its exhibit list.

Deputy Administrator Rannazzissi will further testify in response to Respondent's contention in its Prehearing Statement that its suspicious orders program was modeled on guidance from DEA's website. He will testify that Respondent's reliance on this website is misplaced, as it applies to DEA's Chemical Program only and is designed to implement separate statutes and regulations than those involving suspicious orders for controlled substances.

2. **DPM Langston:**

Ms. Langston will further testify to her review of the materials provided by Respondent in response to a subpoena request for the distributor's due diligence and customer files. Utilizing her training and experience in investigating manufacturers and distributors of controlled substances, she will testify that she found little to no evidence that Respondent or any part of its vertically integrated corporate structure undertook any efforts to assess the reasonableness or legitimacy of the orders it was shipping to Walgreens stores, despite the fact that it routinely identified these orders as suspicious. (To the extent this testimony is duplicative of that

proffered for A/GS Richards, Ms. Langston's testimony on these matters will be in place of Ms. Richards.) Correcting her proffered testimony in the government's Prehearing Statement, Ms. Langston will testify that the last suspicious control drug orders report received by DEA on behalf of Respondent was in February 2012, covering orders through January 2012.

3. Diversion Investigator ("DI") Phyllis Garrett:

DI Garrett (or, in the alternative, GS Richards) will additionally testify that Respondent's Suspicious Order Reports frequently failed to fully report all orders that, pursuant to their own criteria, should have been reported as suspicious. She will identify and describe a chart with supporting documentation, showing examples of these failures, some of which also include failures to report orders of Schedule II drugs to ARCOS. She will similarly identify and describe a summary of orders shipped by Respondent in early 2012, after it adopted a policy of no longer making suspicious order reports on the basis that it would not ship them, that exceeded its 2011 and January 2012 criteria for reporting those orders as suspicious.

DI Garrett (or, in the alternative GS Richards) will identify Walgreens "Oxycodone Action Plan" Memo for District 227 and compare the plan's intent to impose immediate order limits on three stores with the actual orders shipped by Respondent subsequent to this plan.

4. George Corripio

Pharmacist George Corripio will testify that he was temporarily transferred from Fort Pierce Walgreens 5079 to Walgreens Store # 4727, Fort Pierce, Florida, for a brief period in late 2010 (vice 2011 as stated in the Government's Prehearing Statement.) He will testify to the sharp contrast in clientele and dispensing practices between 4727 and 5079, despite their relative close proximity. He will testify that much of Store #4727's oxycodone customers appeared to be young, healthy individuals, whose appearance did not correspond with the medication they were

seeking or the diagnosis codes he obtained from the offices of the clinics issuing the prescriptions. Many times, the customers seeking the pain medications would arrive in groups who all seemed to know each other and they often appeared to be under the influence of something, which was suspicious to him based on his years of experience as a pharmacist. He will testify that the pharmacy supervisor, Andrea Cohen, told him that all he had to do to in order to fill a prescription was to get a diagnosis code from the issuing office. Because of his own discomfort in filling these prescriptions which he readily identified as suspicious, Andrea Cohen offered to fill them for him. He will testify that the offices whose customers presented pain prescriptions at 4727 generally provided the same diagnosis, usually low back pain, and that he observed that if 4727 filled one of these questionable prescriptions, they would soon see several more customers presenting similarly questionable prescriptions. He will testify that many times when he refused to fill these prescriptions, the customers would get angry and ask when the female pharmacist was coming back. He will testify that the majority of these customers paid cash and were encouraged to return to the pharmacy by Supervisor Andrea Cohen, who would offer these customers Walgreens discount cards. He will testify that he told law enforcement officers that the situation at 4727 with regards to the pill-seeking customers was out of control and that he needed help.

He will testify about an incident he reported to the police after he mistakenly provided extra oxycodone to customer Richard Hanson. Upon trying to call Hanson to tell him to return the oxycodone, Hanson's girlfriend told him that Hanson was an addict who sells his pills. He will be asked about whether there is anything in Walgreens dispensing system to note such an incident in order to flag a customer such as Hanson should he present prescriptions in the future for similar substances.

Proposed Exhibits:

Pursuant to the Court's Prehearing Ruling, the Government produced the following proposed exhibits to Respondent on November 30, 2012:

Exhibit	Description	# Pages
1.	DEA Certificate of Registration RW0277752	1
2.	September 27, 2006 Guidance Letter From DEA Deputy Assistant Administrator Joseph T. Rannazzisi to Walgreen Co.	8
3.	December 27, 2007 Guidance Letter From DEA Deputy Assistant Administrator Joseph T. Rannazzisi to Walgreen Co.	4
4.	April 2011 Memorandum of Agreement Between Walgreen Co. and DEA	7
5.	July 1, 2011 Florida State Department of Health Declaration of Public Health Emergency Regarding Prescription Drug Abuse Epidemic	5
6.	October 17, 2008 Healthcare Distribution Management Association Guidance with Attached Letter for DEA Chief Counsel Wendy Goggin	17
7.	February 15, 2005 Walgreens Policy: "Handling Suspicious Drug Orders"	2
8.	Notes on Walgreens Proposed Suspicious Order Policy	2
9.	April 4, 2012 Walgreens Policy: "Handling Suspicious Orders and Loss of Controlled Drugs"	1
10.	April 4, 2012 Walgreens Policy: "Handling Suspicious Drug Orders"	1
11.	Walgreens "Controlled Substance Threshold" Project P09002, February 2009	18
12.	December 2011 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	1626
13.	December 2011 Walgreens Jupiter Distribution Center C3-5 Suspicious Order Report	384

14.	Excerpt of December 2011 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	25
15.	Excerpt of August 2011 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	46
16.	Excerpt of July 2011 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	46
17.	Excerpt of June 2011 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	46
18.	Excerpt of December 2010 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	36
19.	Excerpt of Suspicious Orders for Walgreens #3099	14
20.	Excerpt of Suspicious Orders for Walgreens #3629	64
21.	Excerpt of Suspicious Orders for Walgreens #3836	49
22.	Excerpt of Suspicious Orders for Walgreens #4391	34
23.	Excerpt of Suspicious Orders for Walgreens #4727	19
24.	Excerpt of Suspicious Orders for Walgreens #6997	15
25.	Walgreens Ft. Pierce Comparison of ARCOS Data and Chart	1
26.	Walgreens Oviedo Comparison of ARCOS Data and Chart	1
27.	Walgreens Port Richey and Hudson Comparison of ARCOS Data and Chart	1
28.	Walgreens Ft. Myers Comparison of ARCOS Data and Chart	1
29.	Top 100 Walgreens Purchasers of Oxycodone from Jupiter Distribution Center	3
30.	Yearly Sales of Oxycodone to Select Walgreens Pharmacies from All Sources, 209-2011	1
31.	Orders for 30mg Oxycodone (100 count bottles) in 2012 Exceeding Walgreens 2011 "Trigger Amount" for Reporting Suspicious Transactions, with Attached DEA Forms 222	23
32.	Walgreens Ft. Pierce (#4391) ARCOS Reporting Discrepancies	28
33.	Walgreens Ft. Pierce (#4727) ARCOS Reporting Discrepancies	21
34.	Walgreens Ft. Meyers (#3099) ARCOS Reporting Discrepancies	25
35.	Walgreens Hudson (#3629) ARCOS Reporting Discrepancies	41

36.	Walgreens Oviedo (#6997) ARCOS Reporting Discrepancies	22
37.	Walgreens Port Richey (#3836) ARCOS Reporting Discrepancies	30
38.	Suspicious Order Report Discrepancies	39
39.	DEA Guidance "A Pharmacist's Guide to Prescription Fraud"	2
40.	September 27, 2010 Ft. Pierce Police Incident Report for Richard Frederick Hanson	5
41.	Copies of Prescriptions Filled for Richard Frederick Hanson by Walgreens #4727	10
42.	November 4, 2011 Ft. Pierce Police Incident Report from Walgreens #4727	6
43.	Copies of Prescriptions Filled for Carlo Pastor by Walgreens #4727	18
44.	December 24, 2010 Police Incident Report Regarding James McCune and Accompanying Prescriptions	18
45.	Dispensing Log of Prescriptions Filled by Walgreens #3629 for James McCune	1
46.	Letters sent from Oviedo Police Department to Walgreens	16
47.	Summary of Arrests Made at Walgreens Pharmacies in Oviedo, Florida	1
48.	Summary of Surveillance Conducted at Walgreens Oviedo Pharmacies and Law Enforcement Results	2
49.	Oviedo Clinton and Valerie Brekke Exhibit	30
50.	Oviedo Staci Starling Exhibit	17
51.	March 19, 2012 Administrative Subpoena for Walgreens Due Diligence Files	2
52.	Letters from Walgreens Legal Counsel to DPM Susan Langston Outlining Walgreens' Response to DEA Due Diligence Subpoena	6
53.	Email: FW: The Two Minute Oxy-Refusal [WAG00000368]	2
54.	Email: re_oxycodone 30 mg [WAG00000460]	2
55.	Email: Re_Please advise on Pain Manag [WAG00000462]	2
56.	Email: Standards of Practice for the Disp [WAG00000464]	2
57.	Email: Re_Handling Pain Management RX [WAG00000660]	2

58.	Email: 0969_001a [WAG00000742]	22
59.	Email: 0969_001a [WAG00000742]	22
60.	Email: Fw_DEA issue at 6094 with attachment [WAG00000813]****	8
61.	Email: _ Oxycodone sales with attachment [WAG00000829]	12
62.	Email: District Notes and Focus Points [WAG00000845]	1
63.	Email: Margate FL Schedule II limitations (Svihra) [WAG00000846]	4
64.	Email: Re: High Quantity Stores 682971 [WAG00000869]	11
65.	Email: Ft Pierce.msg 2 [WAG0000889]	13
66.	Email: Rx Numbers – Oviedo FL (Svihra) [WAG00000902]	2
67.	Email: Oviedo FL (Stahmann) [WAG00000904]	3
68.	Email: Re Fw 682971 - OXYCODONE HCL 30MG TAB [WAG0000908]	11
69.	Email: Fw_3099 Oxycodone Issue [WAG00000919]	2
70.	Email: Re Store #3836 [WAG00000921]	4
71.	Email: Re Fw INC000002834005 Store #3836 WIC#682971 order qty 148 [WAG00000925]	4
72.	Email: 1412 - CII Dispensing Action Plan [WAG00000929]	1
73.	Email: 3525 - CII Dispensing Action Plan [WAG00000930]	1
74.	Email: Fw_Stores with many adjustments [WAG00000948]	2
75.	Email: STORE 3099 – RxS Due Diligence [WAG00001042]	3
76.	Email: Re Store #06997 [WAG00001057]	2
77.	Email: Re Fw Oxycontin question [WAG00001064]	8
78.	Email: Re Fw CII Order [WAG00001087]	17
79.	Email: Florida Focus on Profit (Svihra) [WAG00001107] ****	7
80.	Email: Store 4706 [WAG00001125]	7
81.	Email: Dist #227 Oxycodone Memo August 2011 [WAG00001212]	2

82.	Email: Store 3099 [WAG00001256]	1
83.	Email: Re_3099 [WAG00001260]	2
84.	Email: 1009_001 [WAG00001326]	40
85.	Email: REQUEST REVIEW Florida Pain Management Visits (Merten) [WAG00001638]	1

**** Government Exhibits 60 and 79 are subject to the ongoing litigation involving Respondent's privilege claims. They are produced here as redacted by Respondent pending a resolution of the privilege issue.

Proposed Supplemental Exhibits:

86. Email: Actions Taken in District 21 about CII Dispensing WAG0001740 – 2 pages

87. Email: New Florida Prescribing Law – 3 pages

88. Email: Focus on Compliance Survey – 6 pages

89. Focus on Compliance Survey Results – Excel Spreadsheet – 48 pages

90. List of items produced in response to Administrative Subpoena – 13 pages

OTHER MATTERS

1. Testimony by VTC:

The Government has moved to exclude the proffered testimony of DEA employees and/or Task Force Officers Amber Baginski, Roberta Goralczyk, William Schwartz and Roger Kernicky, witnesses 19-22 in Respondent's Prehearing Statement. Should the Court deny the Government's motion as to any of these witnesses, we request that they be allowed to testify by VTC. It is the Government's intention to have Oviedo Police Chief Jeffrey Chudnow testify in

person, however, given his position, we request the opportunity to present his testimony by VTC only if some currently unforeseen circumstance requires that he remain in Florida. We similarly request the opportunity to present the testimony of George Corripio by VTC if necessary to accommodate his employment schedule.

2. Notice of Additional Basis For Revocation:

The ISO and Prehearing Statement allege that Respondent violated federal statutes and regulations by failing to implement a system to properly identify and investigate suspicious orders. The failure to conduct adequate due diligence as part of a distributor's obligation to maintain effective controls against diversion is further alleged as conduct that would render Respondent's registration inconsistent with the public interest under 21 U.S.C. § 824(a)(4). Florida law imposes similar requirements on wholesale distributors to conduct due diligence and develop a program to identify suspicious orders and prevent suspicious transactions. Florida Statutes (FS) 499.0121 (15). In particular, a wholesale distributor must assess the reasonableness of orders in excess of 5,000 unit doses of any one controlled substance in any one month. FS 499.0121 (15)(b). The Government hereby notifies Respondent that the same evidence and testimony already disclosed may therefore also demonstrate that Respondent has failed to comply with applicable State law under 21 U.S.C. §§ 823(b)(2) & § 823(e)(2).

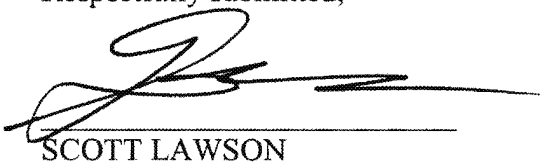
3. **Courtroom presence of Government Expert Witness:**

The Government requests that its noticed expert, Prof. Paul Doering be permitted to observe all aspects of the hearing in the event he is called in rebuttal.

4. **Respondent's Witnesses:**

Similar to Respondent's notice at fn 1 of its Prehearing Statement, the Government reserves the right to call any of Respondent's Witnesses on the matters listed in their proposed testimony.

Respectfully submitted,



SCOTT LAWSON
JONATHAN P. NOVAK
Attorneys
Diversion & Regulatory Litigation
Office of Chief Counsel

Date: December 7, 2012

CERTIFICATE OF SERVICE

I hereby certify that on the date signed below, I caused the original and two copies of the foregoing **GOVERNMENT'S SUPPLEMENTAL PREHEARING STATEMENT**, to be hand delivered and faxed to the DEA Office of the Administrative Law Judges, and I caused a copy of the same to be sent, *via e-mail* to counsel for Respondent at the following addresses:

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12/7/12
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